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February 23, 2007
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Re:	Application of:	Keeven et al.
	Serial No.	10/748,449
	Filed:	December 30, 2003
	For:	Augments for Surgical Instruments
	Group Art Unit:	3733
	Examiner:	Annette R. Reimers
	MMB Docket No.	1671-0281
	J&J Reference:	DEP5038USNP

TRANSMITTAL LETTER

Please find for filing in connection with the above patent application the following documents.

1. Amended Appeal Brief (32 pages); and

2. One (1) return post card.

The $500.00 fee required under 37 C.F.R. §41.20 (b)(2) has previously been submitted. However, please charge any fee deficiency or credit any overpayment to Deposit Account No. 13-0014.

Respectfully Submitted,

MAGINOT, MOORE & BECK

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February 23, 2007

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Enclosures

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

J&J Reference No. **DEP5038USNP**

MMB Docket No. **1671-0281**

Application of: **Keeven et al.**

Group Art Unit: **3733**

Serial No. **10/748,449**

Examiner: **Annette R. Reimers**

Filed: **December 30, 2003**

For: **AUGMENTS FOR SURGICAL INSTRUMENTS**

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AMENDED APPEAL BRIEF

Sir:

This is an appeal under 37 CFR § 41.31 to the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office from the final rejection of the claims 17-32 of the above-identified patent application. These claims were indicated as rejected in an Office Action dated March 20, 2006. The $500.00 fee required under 37 CFR § 41.20(b) (2) was previously submitted. Also, please provide any extensions of

time that may be necessary and charge any fees that may be due to Account No. 13-0014, but not to include any payment of issue fees.

(1) REAL PARTY IN INTEREST

DePuy Products, Inc. of Warsaw, Indiana is the assignee of this patent application, and the real party in interest.

(2) RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences related to this patent application (serial no. 10/748,449).

(3) STATUS OF CLAIMS

Claims 1-16 are cancelled.

Claims 17-32 are pending in the application.

Claims 17-23 were withdrawn by the Examiner.

Claims 28-32 are objected to for informalities.

Claims 24-32 are rejected.

Claims 24-32 are being appealed, and are shown in the Appendix attached to this Appeal Brief.

(4) STATUS OF AMENDMENTS

Appellant has filed no amendments after receipt of the March 20, 2006, Office Action (the "Office Action").

(5) SUMMARY OF CLAIMED SUBJECT MATTER

The present invention relates to a device used to align surgical instruments used in preparing a bone for an implant. (See, e.g. Appellants' specification at page 1, lines 3-5). In accordance with one embodiment, the instrument is a femoral positioner 50. (See, e.g. Appellants' specification at page 8, lines 10-12 and FIG. 4). The femoral positioner 50 includes a surface alignment plate 52 that is configured to rest upon a resected tibia. (See, e.g. Appellants' specification at page 8, lines 12-14 and FIG. 4). The surface alignment plate 52 includes a guide slot 54 which is configured to receive an intramedullary pin that is implanted in the resected tibia (not shown). (See, e.g. Appellants' specification at page 8, lines 14-16 and FIG. 4).

The femoral positioner 52 further includes a connector plate 56 which includes a mating feature which is configured to mate with a corresponding feature (e.g., slot 34) on a resection guide 20. (See, e.g. Appellants' specification at page 8, lines 17-21 and FIGs. 3 and 4).

The femoral positioner 52 also includes bores 64 located on opposite sides of the notch 54 that receive pins 74 on an augment 70. (See, e.g. Appellants' specification at page 9, line 28 through page 10, line 2 and FIGs. 4 and 7). An O-ring 68 is positioned within the bores 64 to provide a frictional fit with the pins 74. (See, e.g. Appellants' specification at page 10, lines 2-7 and FIG. 6).

Accordingly, in a system or method in accordance with the present invention a femoral positioner is placed on a resected tibia and augments are used to provide the

proper gap between the tibia and femur. Thus, the *tibia* is used to orient the *femur*. (See, e.g. Appellants' specification at page 8, lines 27-28).

The additional information required by the United States Patent Office is as follows.

Claim 24

Claim 24 is argued alone. Claim 24 recites:

24. A system for establishing a gap between a femur and a tibia at a knee joint, comprising (see, e.g., Appellants' specification at page 9, lines 9-19):

an instrument having (i) a positioning member that defines a femur facing side and a tibia facing side (see, e.g., Appellants' specification at page 8, lines 12-14 and FIG. 4, reference number 52), said positioning member including a first coupler (see, e.g., Appellants' specification at page 9, line 28 through page 10, line 2 and FIG. 5, reference number 64), and (ii) a connector member having a first mating feature (see, e.g., Appellants' specification at page 8, lines 17-21 and FIG. 4, reference number 56);

an augment (see, e.g., Appellants' specification at page 9, lines 9-10 FIGs. 7 and 8, reference number 70) having a second coupler that cooperates with said first coupler to fix said augment to said positioning member (see, e.g., Appellants' specification at page 10, lines 1-6 and FIGs. 7 and 8, reference number 74); and

a femoral resection guide (see, e.g., Appellants' specification at page 8, lines 17-21 and FIG. 3, reference number 32) having a second mating feature that mates with said first mating feature of said instrument (see, e.g., Appellants' specification at page 8, lines 17-21 and FIG. 3, reference number 23).

Claim 27

Claim 27 is argued alone. Claim 27 depends from claim 24 and recites:

27. The system of claim 24, wherein:

said first coupler of said positioning member includes a bore (see, e.g., Appellants' specification at page 9, line 28 through page 10, line 2 and FIG. 5, reference number 64), and

said second coupler of said augment includes a pin that is received within said bore (see, e.g., Appellants' specification at page 10, lines 1-6 and FIGs. 7 and 8, reference number 74).

Claims 28 and 32

Claims 28 and 32 are argued together. Claim 28 is an independent claim and recites:

A system for establishing a gap between a femur and a tibia at a knee joint, comprising (see, e.g., Appellants' specification at page 9, lines 9-19):

an instrument having a positioning member (see, e.g., Appellants' specification at page 8, lines 12-14 and FIG. 4, reference number 52) that includes a first coupler (see, e.g., Appellants' specification at page 9, line 28 through page 10, line 2 and FIG. 5, reference number 64), said positioning member defining (i) a femur facing side (see, e.g., Appellants' specification at page 8, lines 12-14 and FIG. 4, reference number 52), (ii) a tibia facing side (see, e.g., Appellants' specification at page 8, lines 12-14 and FIG. 4, reference number 52), and (iii), a guide slot configured to receive an intramedullary pin

(see, e.g., Appellants' specification at page 8, lines 14-17 and FIG. 4, reference number 54);

an augment (see, e.g., Appellants' specification at page 9, lines 9-10 FIGs. 7 and 8, reference number 70) having a second coupler that cooperates with said first coupler to fix said augment to said positioning member (see, e.g., Appellants' specification at page 10, lines 1-6 and FIGs. 7 and 8, reference number 74); and

an intramedually pin received within said guide slot of said positioning member of said instrument (see, e.g., Appellants' specification at page 8, lines 14-17).

Claim 31

Claim 31 is argued alone. Claim 31 depends from claim 28 and recites:

31. The system of claim 28, wherein:

said first coupler of said positioning member includes a bore (see, e.g., Appellants' specification at page 9, line 28 through page 10, line 2 and FIG. 5, reference number 64), and

said second coupler of said augment includes a pin that is received within said bore (see, e.g., Appellants' specification at page 10, lines 1-6 and FIGs. 7 and 8, reference number 74).

Claims 25 and 26

Claims 25 and 26 are argued together. Claim 25 depends from claim 24 and recites:

25. The system of claim 24, wherein:

said first coupler of said positioning member includes a bore (see, e.g. Appellants' specification at page 10, lines 2-7 and FIG. 6, reference number 64) having a resilient O-ring positioned therein (see, e.g. Appellants' specification at page 10, lines 2-7 and FIG. 6, reference number 68), and

said second coupler of said augment includes a pin that is in frictional contact with said O-ring (see, e.g., Appellants' specification at page 10, lines 1-6 and FIGs. 7 and 8, reference number 74).

Claims 29 and 30

Claims 29 and 30 are argued together. Claim 29 depends from claim 28 and recites:

29. The system of claim 28, wherein:

said first coupler of said positioning member includes a bore (see, e.g. Appellants' specification at page 10, lines 2-7 and FIG. 6, reference number 64) having a resilient O-ring positioned therein (see, e.g. Appellants' specification at page 10, lines 2-7 and FIG. 6, reference number 68), and

said second coupler of said augment includes a pin that is in frictional contact with said O-ring (see, e.g., Appellants' specification at page 10, lines 1-6 and FIGs. 7 and 8, reference number 74).

(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 24, 27, 28, 31 and 32 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,464,406 to Ritter et al. (hereinafter "Ritter").

Claims 25, 26, 29 and 30 stand rejected as obvious under 35 U.S.C. §103(a) over Ritter in view of U.S. Patent Publication No. 2002/0116009 of Fraser et al. (hereinafter "Fraser").

(7) ARGUMENT

In addition to the arguments set forth below, the arguments set forth by the Applicants in the Reply Brief filed on January 17, 2007 still apply.

Claim 24 is Not Anticipated by Ritter

Discussion re: Patentability of Claim 24

1. Claim 24

Claim 24 recites the following:

> A system for establishing a gap between a femur and a tibia at a knee joint, comprising:
> an instrument having (i) a positioning member that defines a femur facing side and a tibia facing side, said positioning member including a first coupler, and (ii) a connector member having a first mating feature;
> an augment having a second coupler that cooperates with said first coupler to fix said augment to said positioning member; and
> a femoral resection guide having a second mating feature that mates with said first mating feature of said instrument.

Accordingly, claim 24 requires an instrument to have a coupler that couples with a coupler of an augment and a mating feature that mates with a mating feature of a resection guide. The claim further recites that the two couplers cooperate "to fix" the augment to the positioning member.

2. Ritter's Flange is Not a Coupler

The Examiner rejected claim 24 based upon the proposition that Ritter discloses an instrument with a coupler that couples with a coupler of an augment and a mating

feature that mates with a mating feature of a resection guide. (Office Action at page 4). The Examiner has mischaracterized Ritter.

Specifically, the Examiner has alleged that the intramedullary rod 30 of Ritter discloses the claimed instrument. (Office Action at page 4). According to the Examiner, the flange 34 of Ritter is a first coupler and the hex portion 38 of the bore 36 is the first mating feature. (Office Action at page 4). A "flange" is merely a projecting rim. Therefore, merely observing that Ritter discloses a "flange" is not sufficient to determine whether or not the flange of Ritter anticipates the claimed coupler. For example, while a flange can be used as a coupler when a cooperating structure is provided, a flange may additionally or alternatively be used as a structure to increase the strength or rigidity of a device. The Federal Circuit has stated that "[a] reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments." *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989). Therefore, because a "flange" could identify either a coupler or a structure that is not a coupler, depending upon the context, a determination of what Ritter reasonably suggests to one of ordinary skill in the art requires a consideration of the manner in which the flange 34 in the device of Ritter is used.

The only use of the flange 34 identified by Ritter is for "impacting the intramedullary rod 30 into the femur 27." (Ritter at column 4, lines 2-5). Thus, impacting the intramedullary rod 30 is accomplished by inserting the hex portion 50 of the impactor 44 in the hex portion 38 of the intramedullary rod 30 until the shaft of the impactor 44 abuts the flange 34 and then striking the impactor 44 with a mallet 158.

(Ritter at column 7, lines 32-39 and FIG. 5). The intramedullary rod 30 is then impacted until the flange 34 abuts the resected femur. (See, e.g., Ritter at FIG. 11). Thus, the "flange 34" is not a coupling device. Rather, the flange 34 is a structure for receiving an impact.

Accordingly, because the flange 34 of Ritter does not "couple" anything, Ritter does not disclose a first coupler on the positioning member. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Therefore, because the Examiner has failed to identify a first coupler as set forth in the claim, the Board of Appeals is respectfully requested to reverse this rejection of claim 24.

3. The Flange Does Not Fix Anything to the Intramedullary Rod

Moreover, even if the flange of Ritter could be considered to be a coupler, claim 24 requires the first coupler, in combination with a second coupler on an augment, to fix the augment to the instrument. Thus, to anticipate the claimed coupler the flange of Ritter must perform the function recited in the claim. See, e.g., *Phillips v. AWH Corp.*, 415 F.3d 1303, 1324 75 USPQ2d 1321, 1335 (Fed. Cir. 2005) (en banc) (stating that the phrase "for deflecting ..." was a "specific limitation on the term 'baffles' in [the claim]."). The flange of Ritter fails to perform the recited function.

Specifically, the Examiner alleges that the femoral provisional 96 is the claimed augment and the angled support 86 is the second coupler. (Office Action at page 4). Ritter discloses that the angled support 86 is attached to the femoral provisional 96 by

passing the shaft of the screw 100 through the hole 98 in the provisional femoral 96 and threading the screw 100 into the bore 92 of the angled support 86. (Ritter at column 8, lines 26-34 and FIG. 8). Thereafter, the angled support 86 is inserted into the bore 36 of the intramedullary rod 30 "until the angled support member 86 contacts the head 62 of the screw 58." (Ritter at column 9, lines 16-19, see also FIG. 11). Therefore, Ritter only discloses contact between the angled support 86 and both the hex portion of the bore 36 and the head 62 of the screw 58. Ritter never teaches, discloses or suggests that the flange 34 ever contacts the provisional femoral 96 or the angled support 86.

Accordingly, because the flange 34 of Ritter plays no role in "fixing" the provisional femoral 96 to the intramedullary rod 30, Ritter does not disclose a first coupler on the positioning member that performs the function required by the coupler in claim 24. Therefore, because the Examiner has failed to identify a first coupler which possesses the characteristics required by the claim, the Board of Appeals is respectfully requested to reverse this rejection of claim 24.

4. Conclusion

For some or all of the above reasons, Ritter does not anticipate claim 24. Accordingly, the Board of Appeals is respectfully requested to reverse this rejection of claim 24.

Claim 27 is Not Anticipated by Ritter

Discussion re: Patentability of Claim 27

1. Claim 27 depends from Claim 24

As an initial matter, claim 27 depends from and incorporates all the limitations of claim 24. Accordingly, in addition to the reasons discussed below, claim 27 is patentable over the prior art for at least the same reasons as those set forth above in connection with claim 24.

2. Additional Limitations of Claim 27

Claim 27 depends from claim 24 and includes the following limitation:

> The system of claim 24, wherein:
> said first coupler of said positioning member includes a bore, and
> said second coupler of said augment includes a pin that is received within said bore.

Claim 24 thus recites that a pin which is part of the augment is received within a bore of the coupler on the positioning member.

3. Ritter Does Not Disclose a Pin-Bore Coupling as Claimed

The Examiner has alleged that Ritter teaches a pin which is part of the augment that is received within a bore of the coupler on the positioning member. (Office Action at page 4). The Examiner has mischaracterized Ritter.

Specifically, the Examiner alleges that the screw 100 is the "pin" of the angled support 86 (the second coupler) which is received within the bore 36 of the flange 34. (Office Action at page 4). The screw 100, however, is used to couple the angled support 86 to the provisional femoral 96. (Ritter at column 8, lines 26-30). Therefore, the screw

100 is received within the bore of the *angled support 86*, not the bore 36 of the intramedullary rod 30. The Examiner has alleged, however, that the angled support 86 is part of the provisional femoral 96 (augment) not a part of the intramedullary rod 30 (the instrument). Therefore, accepting the Examiner's characterization of the "instrument" and "augment" of Ritter, the alleged "pin" is received in a bore in the augment, not a bore in the instrument as recited in the claim.

Accordingly, because the screw 100 of Ritter is not inserted into the intramedullary rod 30, Ritter does not disclose a pin which is part of the augment that is received within a bore of the coupler on the positioning member. Therefore, Ritter does not anticipate claim 24 and the Board of Appeals is respectfully requested to reverse this rejection of claim 24.

4. The Screw of Ritter Need Not Be Received Into the Intramedullary Rod

Moreover, even when the screw 100 is inserted into the angled support 86 and the angled support 86 is inserted into the bore 36, the screw 100 does not necessarily break the plane of the flange 34 so as to be even arguably "received" in the bore of the intramedullary rod.

As an initial matter, the screw 100 is merely used to attach the provisional femoral 96 to the angled support 86. (Ritter at column 8, lines 26-30). Thus, in order to attach the provisional femoral 96 and the angled support 86, the screw 100 need only be long enough to extend through the provisional femoral 96 and into the angled support 86. Accordingly, whether or not the screw 100 projects past the plane of the flange 34 has no effect on the operability of the device of Ritter

Moreover, Ritter clearly depicts an embodiment wherein the length of the screw 100 is much less than the length of the angled support 86. (See, e.g. Ritter at FIG. 2). Additionally, the angled support 86 is not fully inserted into the bore 36. For example, the effective depth of the bore 36 is controlled by the screw 58. (Ritter at column 4, lines 53-56. Thus, the extent to which the angled support 86 can be inserted into the bore 36 is a variable. (See, e.g., column 8, line 65 to column 9, line 6 and compare FIG. 11 and FIG. 12). Furthermore, when the screw 58 is positioned into the threaded end portion 40 just as much as is necessary to be stable, a comparison of the size of the various components as shown in FIG. 2 reveals that the screw 58 *could not* extend beyond the plane of the flange 34.

While the description of FIG. 2 may not be sufficient to support a comparison of the relative sizes of the components, FIG. 2 clearly illustrates that whether or not the screw 58 breaks the plane of the flange 34, even when the screw 100 is positioned to allow the fullest penetration of the angled support 86 into the bore 36 (see, e.g. Ritter at column 7, lines 55-60) depends upon a number of design factors (e.g., length of the bore 36, length of the screw 58, length of the screw 100, width of the provisional femoral 96 including the flange portion 99 and length of the angled support 86). Therefore, it would be mere happenstance if any structure made according to Ritter resulted in the screw 100 breaking the plane of the flange 34.

An accidental or unwitting duplication of an invention cannot constitute an anticipation. *In re Felton*, 484 F.2d 495, 500; 179 U.S.P.Q. 295, 298 (CCPA, 1973) citing, *Tilghman v. Proctor,* 102 U.S. 707 (1880); *Eibel Process Co. v. Minnesota and*

Ontario Paper Co., 261 U.S. 45 (1923). Therefore, Ritter does not anticipate claim 27 and the Board of Appeals is respectfully requested to reverse this rejection of claim 27.

5. Conclusion

For any or all of the above reasons, it is respectfully submitted that Ritter does not anticipate claim 27 and the Board of Appeals is respectfully requested to reverse this rejection of claim 27.

Claims 28 and 32 are Not Anticipated by Ritter

Discussion re: Patentability of Claim 28

1. Claim 28

Claim 28 recites the following:

> A system for establishing a gap between a femur and a tibia at a knee joint, comprising:
> an instrument having a positioning member that includes a first coupler, said positioning member defining (i) a femur facing side, (ii) a tibia facing side, and (iii), a guide slot configured to receive an intramedullary pin;
> an augment having a second coupler that cooperates with said first coupler to fix said augment to said positioning member; and
> an intramedually pin received within said guide slot of said positioning member of said instrument.

Accordingly, claim 28 requires an instrument to have a coupler that couples with a coupler of an augment and a guide slot that receives an intramedullary pin. Claim 28 further recites an intramedullary pin received within the guide slot.

2. The Discussion of Claim 24 Applies

Claim 28 includes the same first coupler and second coupler limitations that were discussed above with respect to claim 24. The Examiner has apparently relied upon the same components in Ritter in the rejection of claim 28 that were discussed above with

respect to claim 24. Accordingly, in addition to the reasons discussed below, claim 28 is patentable over the prior art for at least the same reasons as those set forth above in connection with the "coupler" elements of claim 24.

3. Ritter Does Not Disclose a Guide Slot

The Examiner rejected claim 28 based upon the proposition that Ritter disclosed a guide slot as recited in claim 28. (Office Action at page 4). Specifically, the Examiner has alleged that the flutes 32 of Ritter are "guide slots." (Office Action at page 4 and 6). While in certain configurations a "flute" can be used as a "guide" claim 28 recites a specific function for the recited guide slots. Thus, to anticipate the claimed guide slot the "flutes" of Ritter must perform the function recited in the claim. See, e.g., *Phillips v. AWH Corp.*, 415 F.3d at 1324, 75 USPQ2d at 1335 (Fed. Cir. 2005) (en banc) (stating that the phrase "for deflecting ..." was a "specific limitation on the term 'baffles' in [the claim]."). The flutes of Ritter fail to perform the recited function of receiving an intramedullary pin.

Specifically, Ritter discloses that the flutes 32 "are used to prevent rotation of he intramedullary rod 30." (Ritter at column 3, line 67 though column 4, line 1). This is accomplished by inserting the intramedullary rod 30 into a canal reamed in the femur 27 until the flutes 32 of the intramedullary rod 30 engage the femur 27 (Ritter at column 7, lines 36-40 and FIGs. 5 and 11). Therefore, the only "thing" that the flutes receive is the femur. Nothing else contacts the flutes 32. A femur is not an intramedullary pin. Therefore, while the flutes 32 are on the intramedullary rod 30, which the Examiner has

alleged is the claimed "instrument," the flutes do not receive an intramedullary pin as recited in the claim.

Accordingly, because the flutes 32 of Ritter do not receive an intramedullary pin as recited in claim 28, Ritter does not disclose a guide slot defined by the positioning member that performs the function required by the claim. Therefore, because the Examiner has failed to identify a guide slot which performs the function as set forth in the claim, the Board of Appeals is respectfully requested to reverse this rejection of claim 28.

4. Anticipation Has Not Been Properly Alleged

Claim 28 also requires "an intramedullary pin." The Examiner has failed to identify any intramedullary pin in the Ritter device. By way of example, the only "pin" identified by the Examiner is that pin that is a coupler.[1] Therefore, because the Examiner has failed to identify each element of the claim in the prior art, the Board of Appeals is respectfully requested to reverse this rejection of claim 28.

5. Conclusion

For some or all of the above reasons, Ritter does not anticipate claim 28. Accordingly, the Board of Appeals is respectfully requested to reverse this rejection of claim 28.

[1] Claim 31 below, which depends from claim 28, recites a pin as a part of the augment coupler. This is the "pin" alleged by the Examiner to be present in Ritter. Therefore, the single pin identified by the Examiner cannot be both the intramedullary pin received by the guide slot and the pin of claim 31.

Discussion re: Patentability of Claim 32

Claim 32 depends from and incorporates all the limitations of claim 28. Accordingly, claim 32 is patentable over the prior art for at least the same reasons as those set forth above in connection with claim 28.

Claim 31 is Not Anticipated by Ritter

Discussion re: Patentability of Claim 31

1. Claim 31 depends from Claim 28

As an initial matter, claim 31 depends from and incorporates all the limitations of claim 28. Accordingly, in addition to the reasons discussed below, claim 31 is patentable over the prior art for at least the same reasons as those set forth above in connection with claim 28.

2. Additional Limitations of Claim 31

Claim 31 depends from claim 28 and includes the following limitation:

> The system of claim 28, wherein:
> said first coupler of said positioning member includes a bore, and
> said second coupler of said augment includes a pin that is received within said bore.

Claim 31 thus recites that a pin which is part of the augment is received within a bore of the coupler on the positioning member. This is the same element that was discussed above with respect to claim 27. Therefore, for the same reasons set forth above with respect to the pin and bore limitations of claim 27, claim 31 is patentable over the prior art.

3. Conclusion

For any or all of the above reasons, it is respectfully submitted that Ritter does not anticipate claim 31 and the Board of Appeals is respectfully requested to reverse this rejection of claim 31.

Claims 25 and 26 are Not Obvious Over Ritter in view of Fraser

Discussion Regarding Claim 25

1. The Discussion of Claim 24 Applies

As an initial matter, claim 25 has been rejected as obvious over Ritter in view of Fraser based primarily upon Ritter with reference to Fraser for teaching O-rings. (Office Action at page 5). Claim 25 depends from claim 24 and incorporates all of the limitations of claim 24. As discussed above, Ritter fails to disclose each element of claim 24. Therefore, even if Ritter is modified to incorporate the O-rings of Fraser, such modification fails to correct the deficiencies of Ritter as discussed above. Thus, for at least the same reasons set forth above with respect to the patentability of claim 24 over Ritter, claim 25 is patentable over the proposed combination of Ritter in view of Fraser and the Board of Appeals is respectfully requested to reverse the rejection of claim 25.

2. Additional Limitations of Claim 25

Claim 25 depends from claim 24 and includes the following limitation:

> The system of claim 24, wherein:
> said first coupler of said positioning member includes a bore having a resilient O-ring positioned therein, and
> said second coupler of said augment includes a pin that is in frictional contact with said O-ring.

Claim 25 thus recites that a pin which is part of the augment is in frictional contact with an O-ring in a bore of the coupler of the positioning member.

3. Ritter Does Not Disclose a Resilient Member

The Examiner has cited to Ritter for teaching a resilient member with reference to Fraser for teaching that a resilient member could be in the form of a threaded region or an O-ring. (Office Action at page 5). The Examiner has mischaracterized both Ritter and Fraser.

a. Fraser is Directed to Engagement Elements

As an initial matter, the Examiner states that "Fraser et al. further shows that the resilient member can be a threaded region or an o-ring." (Office Action at page 5). The Examiner further alleges that Fraser "teaches that [threaded regions and o-rings] are functionally equivalent structures." (Office Action at page 5). The teaching of Fraser has been mischaracterized and over-generalized.

Fraser fails to identify any resilient threaded region. Fraser actually teaches that as an alternative to a threaded region, an O-ring may be used. (Fraser at paragraph 62). Significantly, the alternative structures identified by Fraser are for "engagement elements." (Fraser at paragraph 62, see also FIG. 19a). Therefore, Fraser does not teach that a resilient member can be threaded or an O-ring. Rather, Fraser teaches that two components may be engaged using threaded elements (presumably rigid) or using O-rings (presumably resilient).

Moreover, Fraser cannot be fairly read to teach that a threaded engagement is "functionally equivalent" to an engagement using an O-ring in all situations. The relative strength possible with the two approaches clearly refutes such a reading. Rather, Fraser may reasonably be said to teach that for the particular portion of the apparatus described by Fraser, either mode of engagement would work.

b. Ritter Does Not Disclose a Resilient Member

The Examiner further alleged that the threaded end portion 40 of the bore 36 in the intramedullary rod 30 of Ritter is a "resilient member." (Office Action at page 4). There is no support for the Examiner's conclusion in Ritter.

Specifically, the description of Ritter fails to specifically identify the material used to fabricate the intramedullary rod 30 or to expressly state whether the intramedullary rod is resilient or rigid. Nonetheless, as shown, e.g., in FIG. 11, the intramedullary rod 30 is striped in a manner indicating that it is made from metal. Moreover, since the intramedullary rod 30 is hammered into the femur (see, e.g., Ritter at column 7, lines 32-39 and FIG. 5) and since the flutes 32, which are made of the same material as the threaded end portion 40, penetrate the femur without any apparent deformation, the only reasonable conclusion is that the intramedullary rod 30 is rigid.

Therefore, because the intramedullary rod 30 is rigid, and because the threaded end portion 40 of the intramedullary rod is made of the same material as the rest of the intramedullary rod 30 (see FIG. 11), the threaded end portion 40 cannot reasonably be described as "resilient."

c. There is No Motivation for the Proposed Modification

Accordingly, because the Examiner's proposed motivation for the modification of Ritter was based upon an O-ring being the equivalent of a resilient threaded region, and because neither Ritter nor Fraser disclose a resilient threaded region, the Examiner has failed to provide any motivation for replacing the rigid threaded region of Ritter with the resilient O-ring of Fraser.

d. The Proposed Modification Fails to Arrive at the Invention of Claim 25

Moreover, modification of the threaded end portion 40 of the intramedullary rod 30 to be a resilient O-ring fails to arrive at the claimed invention. Specifically, the claim recites that the pin of the augment is in frictional contact with the O-ring. The threaded end portion 40 of Ritter, however, is *only* in contact with the screw 58. Neither the provisional femoral 96 (which the Examiner alleges to be an augment) nor the angled support 86 ever contacts the threaded end portion 40.

Therefore, modification of the device of Ritter to hold the screw 58 with a resilient O-ring fails to arrive at the claimed invention wherein a part of an augment is in frictional contact with an O-ring. Therefore, the Examiner has failed to present a *prima facie* case of obviousness and the Board of Appeals is respectfully requested to reverse the rejection of claim 25 under 35 U.S.C. § 103(a).

e. The Proposed Modification Renders Ritter Inoperable

Finally, the replacement of the threaded end portion 40 of Ritter with an O-ring renders the device of Ritter unsuitable for its intended purpose. Specifically, the threaded

end portion 40 is used in conjunction with the screw 58 to for adjusting the effective depth of the bore 36. (Ritter at column 4, lines 53-60). The depth of the bore 36 is used to adjust the gaps between the provisional femoral 96 and the spacer block 104. (Ritter at column 8, lines 61-67). The adjustment is critical to the ultimate fit achieved with the prosthesis. Accordingly, the adjustments are made based upon the number of turns made to the screw 58 with the hex driver 160. (Ritter at column 9, lines 2-10).

Therefore, by using a rigid screw in a rigid threaded portion, very fine control over the adjustment of the relative positioning of the provisional femoral 96 and the spacer 104 may be achieved. In contrast, a friction fit using a resilient O-ring would require repeated attempts to achieve the desired degree of insertion. Specifically, as a pin is inserted, the resilient O-ring is deformed both in the direction that the pin is being pushed and outwardly. When the force on the pin is removed, the O-ring will attempt to return to its original shape. Thus, the O-ring will move the pin in the direction opposite to which the pin was originally being moved. The extent of this resilient movement will vary depending upon the size of the components, the resiliency of the O-ring, and the manner in which the O-ring is deformed at the precise moment of release. Therefore, an operator would not be able to precisely ascertain the final position of the pin after pressure on the pin is released.

Moreover, the threaded end portion 40 and screw 58 function as a stop. To this end, the angled support 86 is inserted until its movement is stopped by impact with the screw 58. (Ritter at column 9, lines 16-19). Obviously, if a stop is only maintained in position by a friction fit with an O-ring, the stop may be easily moved when the angled support 86 contacts the stop. This would result in a misalignment of the joint which may

not be discovered until the prosthetic devices were implanted. Such misalignment would necessitate replacement of the prosthetic devices. Thus, the procedure would need to be repeated with new devices, thereby unduly extending the duration of the operation and unacceptably increasing risks to the patient.

Accordingly, because the modification of Ritter proposed by the Examiner renders the device of Ritter unsuitable for its intended purpose, there is no motivation for the proposed modification. Therefore, the Examiner has failed to present a *prima facie* case of obviousness and the Board of Appeals is respectfully requested to reverse the rejection of claim 25 under 35 U.S.C. § 103(a).

4. Conclusion

For any or all of the above reasons, it is respectfully submitted that claim 25 is not obvious over Ritter in view of Fraser and the Board of Appeals is respectfully requested to reverse the rejection of claim 25 under 35 U.S.C. § 103(a) based upon the combination of Ritter and Fraser.

Discussion re: Patentability of Claim 26

Claim 26 depends from and incorporates all the limitations of claim 25. Accordingly, claim 26 is patentable over the prior art for at least the same reasons as those set forth above in connection with claim 25.

Claims 29 and 30 are Not Obvious Over Ritter in view of Fraser

Discussion Regarding Claim 29

1. The Discussion of Claim 28 Applies

As an initial matter, claim 29 has been rejected as obvious over Ritter in view of Fraser based primarily upon Ritter with reference to Fraser for teaching O-rings. (Office Action at page 5). Claim 29 depends from claim 28 and incorporates all of the limitations of claim 28. As discussed above, Ritter fails to disclose each element of claim 28. Therefore, even if Ritter is modified to incorporate the O-rings of Fraser, such modification fails to correct the deficiencies of Ritter as discussed above. Thus, for at least the same reasons set forth above with respect to the patentability of claim 28 over Ritter, claim 29 is patentable over the proposed combination of Ritter in view of Fraser and the Board of Appeals is respectfully requested to reverse the rejection of claim 29.

2. Additional Limitations of Claim 29

Claim 29 depends from claim 28 and includes the following limitation:

> The system of claim 28, wherein:
> said first coupler of said positioning member includes a bore having a resilient O-ring positioned therein, and
> said second coupler of said augment includes a pin that is in frictional contact with said O-ring.

Claim 29 thus recites that a pin which is part of the augment is in frictional contact with an O-ring in a bore of the coupler of the positioning member. This is the same element that was discussed above with respect to claim 25. Therefore, for the same reasons set forth above with respect to the resilient O-ring limitations of claim 25, claim 29 is patentable over the prior art.

3. Conclusion

For any or all of the above reasons, it is respectfully submitted that claim 29 is not obvious over Ritter in view of Fraser and the Board of Appeals is respectfully requested to reverse the rejection of claim 29 under 35 U.S.C. § 103(a) based upon the combination of Ritter and Fraser.

Discussion re: Patentability of Claim 30

Claim 30 depends from and incorporates all the limitations of claim 29. Accordingly, claim 30 is patentable over the prior art for at least the same reasons as those set forth above in connection with claim 29.

The Objections

The Examiner objected to claims 26 and 30 as allegedly being directed to a method and not a system. Claims 26 and 30 recite structural limitations of a groove within a bore and the location of an O-ring. Therefore, the Board is respectfully requested to direct the Examiner to withdraw the objections to claims 26 and 30.

(8) CONCLUSION

Claims 24, 27, 28, 31 and 32 are not anticipated by Ritter and claims 25, 26, 29 and 30 are not obvious over Ritter in view of Fraser. Accordingly, the Board of Appeals is respectfully requested to reverse the rejections of claims 24-32.

Respectfully submitted,

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(9) CLAIMS APPENDIX

Claim 24. A system for establishing a gap between a femur and a tibia at a knee joint, comprising:

an instrument having (i) a positioning member that defines a femur facing side and a tibia facing side, said positioning member including a first coupler, and (ii) a connector member having a first mating feature;

an augment having a second coupler that cooperates with said first coupler to fix said augment to said positioning member; and

a femoral resection guide having a second mating feature that mates with said first mating feature of said instrument.

Claim 25. The system of claim 24, wherein:

said first coupler of said positioning member includes a bore having a resilient O-ring positioned therein, and

said second coupler of said augment includes a pin that is in frictional contact with said O-ring.

Claim 26. The method of claim 25, wherein:

said bore defines an internal groove, and

said O-ring is positioned within said internal groove.

Claim 27. The system of claim 24, wherein:

said first coupler of said positioning member includes a bore, and

said second coupler of said augment includes a pin that is received within said bore.

Claim 28. A system for establishing a gap between a femur and a tibia at a knee joint, comprising:

an instrument having a positioning member that includes a first coupler, said positioning member defining (i) a femur facing side, (ii) a tibia facing side, and (iii), a guide slot configured to receive an intramedullary pin;

an augment having a second coupler that cooperates with said first coupler to fix said augment to said positioning member; and

an intramedually pin received within said guide slot of said positioning member of said instrument.

Claim 29. The system of claim 28, wherein:

said first coupler of said positioning member includes a bore having a resilient O-ring positioned therein, and

said second coupler of said augment includes a pin that is in frictional contact with said O-ring.

Claim 30. The method of claim 29, wherein:

said bore defines an internal groove, and

said O-ring is positioned within said internal groove.

Claim 31. The system of claim 28, wherein:

said first coupler of said positioning member includes a bore, and

said second coupler of said augment includes a pin that is received within said bore.

Claim 32. The system of claim 28, wherein said instrument further has a handle extending from said positioning member.

(10) EVIDENCE APPENDIX

None.

(11) RELATED PROCEEDINGS APPENDIX

None.